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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/516,493	03/01/2000	Maureen J. Charron	96700/613	3363

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EXAMINER
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KAUSHAL, SUMESH

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 11/22/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/516,493

Applicant(s)

CHARRON ET AL.

Examiner

Sumesh Kaushal Ph.D.

Art Unit

1636

--Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 25 October 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_.

3. ☒ Applicant's reply has overcome the following rejection(s): Claim 48, under 35 USC 112(1) regarding new matter issues.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: none.Claim(s) objected to: none.Claim(s) rejected: 44-72.Claim(s) withdrawn from consideration: none.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

Claims 44-72 stand rejected under 35 U.S.C. 101 and 35 USC 112 (1) regarding lack of specific utility and enablement issue for the same reasons of record as set forth in the office action mailed on 08/28/02. The applicant argues that the specification provides sufficient evidence to establish to the skilled artisan that the SEQ ID NO:6, 9 and 11 (GLUTx) are portion of sequence encoding human, mouse and rat versions of a novel member of the GLUT family. The applicant argues that based upon sequence similarity the GLUTx is a member of GLUT-family (response, pages 4-5). The applicant further argues that the GLUTx can be used as a marker of diabetes and hyperglycemia (response, page 6), therefore invention as claimed has specific and well established utility. However, this is not found persuasive because the specification fails to establish that the polynucleotide sequences as claimed encode a protein which is a member of glucose transporter/sensor/receptor family as shown by structural and/or functional properties. The art at the time of filing teaches that the GLUTs form a family of highly related hexose transport proteins that belongs to a larger sugar transport superfamily consisting of more than 133 members distributed in a wide variety of species (see pages 4-6 office action 08/28/02). At best the instant specification only discloses pieces of GLUTx-like amino acid sequences isolated from human, mouse and rat. The specification as filed fails to disclose that these partial sequences have any GLUTx-like activity explicitly or implicitly as putatively considered by the instant specification. The instant specification even fails to disclose an assay, which measures the biological activity of GLUTx polypeptides (as claimed). The only unlimited use for the disclosed polynucleotide sequences would be the determination of what is the biological activity of the polypeptide encoded by the claimed polynucleotides and further search on how to use the discovered protein. Similarly, the instant specification fails to disclose that a nucleotide sequence which hybridize under stringent hybridization conditions to a nucleotide sequence selected from SEQ ID NO: 6, 9 and 11 have any GLUT1, GLUT2, GLUT3, GLUT4 or GLUT5 like activity. The Office sequence search using the disclosed amino acid sequences matches with GLUTX3 consensus sequences (AN: AAB66941) SEQ ID NO:7 (40%), SEQ ID NO:10 (31%) and SEQ ID NO:12 (42%), but only with very low sequence similarity. Similarly, SEQ ID NO:7 (23%) and SEQ ID NO:12 (30%) matches with GLUTX2 amino acid sequences (AN: AAB66940, AAB66936 respectively), but only with very low sequence similarity. Considering the state of art and degree of sequence similarity, the only immediate apparent utility for the instant invention would be its further scientific characterization as a putative glucose transporter/sensor/receptor. Therefore, the asserted use for the claimed nucleic acid is not considered to support by either a specific and/or substantial utility, since no function can be ascribed to the gene.

Claims 44-47 stand rejected under 35 U.S.C. 112, first paragraph, regarding written description issues for the same reasons of record as set forth in the office action mailed on 08/28/02. The applicant argues that the inventors are in the possession of invention as claimed since the specification describes high stringency conditions (response, page 8). However, this is not found persuasive because disclosure of a single species is rarely, if ever, sufficient to describe a broad genus, particularly when the specification fails to describe the features of that genus, even in passing. (see *In re Shokal* 113USPQ283(CCPA1957); *Purdue Pharma L. P. vs. Faulding Inc.* 56 USPQ2nd 1481 (CAFC 2000)). In claims to genetic material, generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not adequate written description of claimed genus, since it does not distinguish genus from others except by function, and does not specifically define any of genes that fall within its definition, or describe structural features commonly possessed by members of genus that distinguish them from others; accordingly, naming type of material generally known to exist, in absence of knowledge as to what that material consists of, is not description of that material (*Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406). In the instant case the GLUTx polypeptide (as claimed) has been defined only by a statement of function of glucose transporter-like activity, which conveyed no distinguishing information about the identity of the claimed DNA sequence, such as its relevant structural or physical characteristics. Furthermore, the invention as claimed encompasses any and all natural and non-natural variants of SEQ ID NO: 6, 9 and 11 obtained from any and all organisms. At best, the specification discloses only one variant each for human mouse and rat within the scope of genus comprising the claimed SEQ ID NO:6, 9 and 11. According to these facts, one skill in the art would conclude that applicant was not in the possession of the claimed genus because a description of only one member of this genus is not representative of the variants of genus and is insufficient to support the claim.

*Scott D. Pribe*

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PRIMARY EXAMINER